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PATENT  
2059-0103P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Harold G. BROWN et al. Conf.: 1812  
Appl. No.: 09/890,425 Group: 1651  
Filed: February 19, 2002 Examiner: PRATS  
For: A PHARMACEUTICAL COMPOSITION OF COMPLEX  
CARBOHYDRATES AND ESSENTIAL OILS AND  
METHODS OF USING THE SAME

INFORMATION DISCLOSURE STATEMENT  
(SUBMISSION AFTER FILING OF AN APPLICATION  
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE  
OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

March 29, 2005

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-1449(s), attached hereto.

II. COPIES (check at least one box)

- a. ☒ Copies of cited U.S. patents and patent application publications are not included. Copies of foreign patent documents and non-patent literature are included.
- b. ☐ Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

III. CONCISE EXPLANATION OF THE RELEVANCE  
(check at least one box)

a. ☒ **DOCUMENTS IN THE ENGLISH LANGUAGE**

The patents, publications, or other information listed on the attached PTO 1449 are in the English language and therefore, do not require a statement of relevancy.

b. ☐ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

c. ☐ **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

d. ☒ **OTHER**

The following additional information is provided for the Examiner's consideration.

Information Under Seal includes Complaints, Answers, Counterclaims, Responses, Expert Rebuttal, Claim Construction, Suggestions, and various Depositions in a pending litigation together with additional PTO-1449 forms.

FEES

IV. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b):  
(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. *(This section is not to be used with RCE's.)*
- b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c. ☐ concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- d. ☐ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required.  
In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):  
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

- a. ☐ No statement; therefore, a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
- or
- b. ☐ See the statement below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or
- b. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- c. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- d. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VII. PAYMENT OF FEES (check one box)

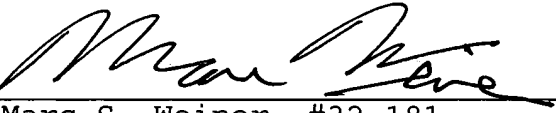
- ☐ A check in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- ☐ Please charge Deposit Account No. 02-2448 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. This paper is submitted in triplicate.
- ☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

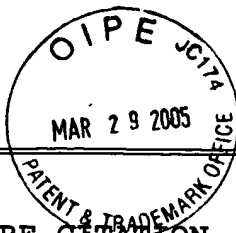
BIRCH, STEWART, KOLASCH & BIRCH, LLP

By   
Marc S. Weiner, #32,181

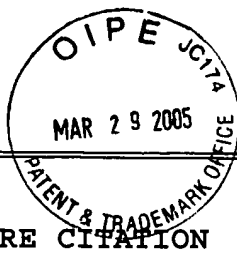
MSW/jmb  
2059-0103P

P.O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000

Attachment(s): ☒ PTO-1449  
☒ Documents  
☐ Foreign Search Report  
☐ Fee  
☐ Other:



Form PTO-1449				ATTY. DOCKET NO. 2059-0103P		APPLICATION NO. 09/890,425			
<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> (Use several sheets if necessary)				APPLICANT Harold G. BROWN et al.					
				FILING DATE February 19, 2002		GROUP 1651			
<b>U.S. PATENT DOCUMENTS</b>									
EXAMINER INITIAL	DOCUMENT NUMBER	Kind	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
	US 4,248,861		02-03-1981	SCHUTT					
	US 4,474,763		10-02-1984	LUBOWE					
	US 4,707,354		11-17-1987	GARLEN et al.					
	US 5,013,726		05-07-1991	IVY et al.					
	US 5,073,366		12-17-1991	BECK					
	US 4,973,473		11-27-1990	SCHNEIDER et al.					
<b>FOREIGN PATENT DOCUMENTS</b>									
	Office	DOCUMENT NUMBER	Kind	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
	JP	S62-77308		04-09-1987	JAPAN			YES	NO
<b>OTHER DOCUMENTS</b> (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)									
	DAVID C. STEINBERG, <i>Cosmetic Technology</i> . Mucopolysaccharides for cosmetics, (February 1982), pp.41-44,								
	Article: Essense Oils, 2 pages								
	Chemistry 470-"Industrial Chemistry", Spring 2004, Internet, 6 pages.								
	SRIVAS R. SRINIVAS, <i>Atlas of Essential Oils</i> , 2 pages.								
	D. KOBAYASHI et al., <i>Pharmaceutical Research</i> , Vol. 11, No. 1, 1994, <u>Analysis of the Combined Effect of 1-Menthol and Ethanol as Skin Permeation Enhancers Based on a Two-Layer Skin Model</u> (article), received 12-4-1992 - accepted 6-22-1993; pp.96-103,								
	HANS SCHAEFER et al.; <u>Skin Barrier</u> (article), 3 pages, Karger								
	Claire PARISEL et al., <u>Interactions of heparin with human skin cells: Binding, location, and transdermal penetration</u> (article); Received 11-5-2002, Accepted 3-4-2003; pp.517-523; 2003 <i>Wiley Periodicals, Inc.</i>								
	PANKAJ KARANDE et al., , <i>Nature Biotechnology-Advance Online Publication</i> , <u>Discovery of transdermal penetration enhancers by high-throughput screening</u> (article), published online (1-4-2004), pp.1-6.								
	GREGORY M. GLENN et al., <i>Nature</i> Vol. 391, <u>Skin immunization made possible by cholera toxin</u> (article), (February 26, 1998), 1 page,								
	GREGORY M. GLENN et al., <i>Cutting Edge</i> , <u>Cutting Edge: Transcutaneous Immunization with Cholera Toxin Protects Mice Against Lethal Mucosal Toxin Challenge</u> (article), pp.3211-3214.								
EXAMINER					DATE CONSIDERED				
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.									



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								YES	NO

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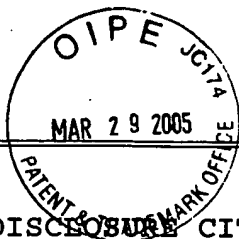
(Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.

	TANYA SCHARTON-KERSTEN et al., <i>Infection and Immunity</i> , Vol. 68, No. 9, Transcutaneous Immunization with Bacterial ADP-Ribosylating Exotoxins, Subunits, and Unrelated Adjuvants (Sept. 2000), pp.5306-5313
	GREGOR CEVC et al., <i>Biochimica et Biophysica Acta</i> , Vol. 1368, (1998), Ultraflexible vesicles, Transfersomes, have an extremely low pore penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin, pp.201-215.
	RAGHAVACHARI et al., <i>Journal of Pharmaceutical Sciences</i> , Vol. 91, No. 3, (March 2002), Targeted Gene Delivery to Skin Cells In Vivo: A Comparative Study of Liposomes and Polymers as Delivery Vehicles, 9 pages.
	MARC COHEN et al., <i>The Journal of Rheumatology</i> , Vol. 30, No. 3, (2003) A Randomized, Double Blind, Placebo Controlled Trial of a Topical Cream Containing Glucosamine Sulfate, Chondroitin Sulfate, and Camphor for Osteoarthritis of the Knee, pp523-528
	MARIE CURIE and the Science of Radioactivity - Research Breakthroughs (1897-1904) 2 pages; 2000-2004 American Institute of Physics.

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(Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)

	NATUROPATHIC LABORATORIES INTERNATIONAL, INC., Plaintiff, v. DERMAL RESEARCH LABORATORIES, INC., Defendant, <u>Complaint</u> , 8 pages, U.S. District Court for the Western District of Missouri Western Division.
	NATUROPATHIC LABORATORIES INTERNATIONAL, INC., Plaintiff, v. DERMAL RESEARCH LABORATORIES, INC., Defendant, <u>Dermal Research Laboratories, Inc.'s Answer and Counterclaim to Naturopathic Laboratories International Inc.'s Complaint</u> , 14 pages, U.S. District Court for the Western District of Missouri Western Division.
	NATUROPATHIC LABORATORIES INTERNATIONAL, INC., Plaintiff, v. DERMAL RESEARCH LABORATORIES, INC., Defendant, <u>Reply of Naturopathic Laboratories International, Inc., to Counterclaim of Dermal Research Laboratories, Inc.</u> , 6 pages, U.S. District Court for the Western District of Missouri Western Division.
	NATUROPATHIC LABORATORIES INTERNATIONAL, INC., Plaintiff, v. DERMAL RESEARCH LABORATORIES, INC., Defendant, <u>Plaintiff Naturopathic Laboratories, International, Inc.'s Response to Defendant's First Set of Interrogatories</u> , 14 pages, U.S. District Court for the Western District of Missouri Western Division.
	DAVID C. STEINBERG, Report, 25 pages.
	DR. KAREN K. BROWN, Notes: D000459 and D000460; 1-9-1992 & 1-18-2002; 2 pages.
	NATUROPATHIC LABORATORIES INTERNATIONAL, INC., Plaintiff, v. DERMAL RESEARCH LABORATORIES, INC., Defendant, <u>Expert Rebuttal to the Invalidity Report of March 8, 2004, Regarding United States Patent Number 5,888,984</u> , 4-9-2004, 27 pages.
	THE 1998 CIR EXPERT PANEL MEMBERS: CHAIRMAN WILMA BERGFELD, MD, FACP, DONALD BELSITO, MD, WILLIAM CARITON, PHD., DVM. CURTIS KLAASSEN, PHD., ARNOLD L. SCHROETER, MD, AND RONALD C. SHANK, PHD., AND THOMAS SAGA, PHD, CIR DIRECTOR: f. ALAN ANDERSEN, PHD, <u>Final Report: Safety Assessment of Peppermint</u> , 9-11-1998, 18 pages, <u>Cosmetic Ingredient Review</u> - Washington, DC;
	NATUROPATHIC LABORATORIES INTERNATIONAL, INC., Plaintiff, v. DERMAL RESEARCH LABORATORIES, INC., Defendant, <u>Claim Construction of '984 Patent</u> ; 1-23-2004; 11 pages; U.S. District Court for the Western District of Missouri Western Division.

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	NATUROPATHIC LABORATORIES INTERNATIONAL, INC., Plaintiff, v. DERMAL RESEARCH LABORATORIES, INC., Defendant, <u>Suggestions in Support of Dermal Research Laboratories, Inc.'s Motion for Summary Judgment on Naturopathic Laboratories International, Inc.'s Invalidity Defenses</u> ; 6-7-2004; 27 pages; U.S. District Court for the Western District of Missouri Western Division.
	NATUROPATHIC LABORATORIES INTERNATIONAL, INC., Plaintiff, v. DERMAL RESEARCH LABORATORIES, INC., Defendant, <u>Deposition of Harold Brown, Ph.D.</u> , 02-26-2004; 335 pages (copied in quarters); U.S. District Court for the Western District of Missouri Western Division.
	NATUROPATHIC LABORATORIES INTERNATIONAL, INC., Plaintiff, v. DERMAL RESEARCH LABORATORIES, INC., Defendant, <u>Deposition of Karen Brown, Ph.D.</u> ; 10-23-2003; 335 pages (copied in quarters); U.S. District Court for the Western District of Missouri Western Division.
	NATUROPATHIC LABORATORIES INTERNATIONAL, INC., Plaintiff, v. DERMAL RESEARCH LABORATORIES, INC., Defendant, <u>Deposition of Carol Cooper, Ph.D.</u> ; 02-17-2004; 339 pages (copied in quarters); U.S. District Court for the Western District of Missouri Western Division.

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